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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/732,869	12/10/2003	Robert A. Rabiner	20563/2144B	6853
29934	7590	05/17/2004		
PALMER & DODGE, LLP RICHARD B. SMITH 111 HUNTINGTON AVENUE BOSTON, MA 02199			EXAMINER VAN, QUANG T	
			ART UNIT 3742	PAPER NUMBER

DATE MAILED: 05/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/732,869

Applicant(s)

RABINER ET AL.

Examiner

Quang T Van

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 27-35 is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-12, 14-23, 25 and 26 is/are rejected.
- 7) ☒ Claim(s) 3, 13 and 24 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 12/10/03.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1, 4-8, 11-12, 15-18, 20-22 and 25-26 are rejected under 35 U.S.C. 102(e) as being anticipated by Flaherty et al (US 6,283,951) cited by applicant. Flaherty discloses a transvascular system comprising a sheath (col. 19, lines 29-33) engaging a body portion of a handle (50), the sheath having an outer end and an inner end (figures 9C-D); a fitting (52) supported by the handle (50) and engaging the sheath; a flexible catheter (12) engaging the handle (50) and extending through the sheath, the flexible catheter (12) having opposite open ends (34) with a distal end (30) of the flexible catheter (12) engaging a shape a shape memory catheter tip (64, col. 10, line 49); a medical device (62) inserted within the flexible catheter (12); and a first lock (70) supported by the handle (50) for adjusting a force required for longitudinal movement of the flexible catheter (12) relative to the sheath and for locking the flexible catheter relative to sheath along a longitudinal axis of the sheath (col. 10, lines 35-39).

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Flaherty et al (US 6,283,951) in view of Accisano, III (US 5,571,085). Flaherty discloses substantially all features of the claimed invention except the flexible catheter is disposable. Accisano discloses a steerable catheter is disposable (col. 13, lines 12-14). It would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize in Flaherty a flexible catheter is disposable as taught by Accisano in order to provide for single patient use.

5. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Flaherty et al (US 6,283,951) in view of Rebell (US 4,917,104). Flaherty discloses substantially all features of the claimed invention except a distal end of the shape memory catheter tip is rounded. Rebell discloses a distal end of the shape memory catheter tip (16) is rounded (col. 3, lines 41-43). It would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize in Flaherty a distal end of the shape memory catheter tip is rounded as taught by Rebell in order to avoid puncturing or tearing tissue.

6. Claims 2, 14, 19 and 23 rejected under 35 U.S.C. 103(a) as being unpatentable over Flaherty et al (US 6,283,951) in view of Willard et al (US 4,846,174). Flaherty discloses substantially all features of the claimed invention except the body portion of the handle being adapted to be grasped and rotated to lock the first lock. Willard discloses a body portion of the handle being adapted to be grasped and rotated to lock

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the first lock (col. 5, lines 67-68 and col. 6, lines 1-3). It would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize in Flaherty a body portion of the handle being adapted to be grasped and rotated to lock the first lock as taught by Willard in order to lock the catheter along the axis of the sheath.

7. Claims 3, 13, and 24 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

8. Claims 27-35 are allowed.

9. The following is a statement of reasons for the indication of allowable subject matter: the prior art of record does not show or suggest the combination of the steps of locking the flexible catheter relative to the sheath with a first lock; inserting the medical device through a proximal end of the flexible catheter at a proximal end of the steerable catheter device; advancing the medical device to the treatment site; locking the medical device relative to the flexible catheter with a second lock; and removing the guidewire from the vasculature of the body as recited in claims 27-35.

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Cassidy et al (US 6,017,340) discloses a pre-curved wire guided papillotome having a shape memory tip for controlled bending and orientation. Grabek et al (US 6,231,518) discloses methods and devices for diagnosis and treatment of cardiac condition through pericardial space.

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11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang T Van whose telephone number is 703-306-9162. The examiner can normally be reached on 8:00Am 7:00Pm M-Th.

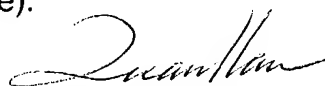
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Denise Pothier can be reached on 703-308-0265. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RT

QV

May 13, 2004



Quang T Van  
Primary Examiner  
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